IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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| NEW ENGLAND CARPENTERS HEALTH BENEFITS FUND, PIRELLI ARMSTRONG RETIREE MEDICAL BENEFITS TRUST, TEAMSTERS HEALTH & WELFARE FUND OF PHILADELPHIA AND VICINITY, PHILADELPHIA FEDERATION OF TEACHERS HEALTH AND WELFARE FUND, and DISTRICT COUNCIL 37 HEALTH & SECURITY PLAN,<br><br>Plaintiffs,<br><br>v.<br><br>FIRST DATABANK, INC., a Missouri corporation, and MCKESSON CORPORATION, a Delaware corporation,<br><br>Defendants. | Case No. 1:05-CV-11148-PBS |

**MEMORANDUM IN OPPOSITION TO JOINT MOTION FOR PRELIMINARY APPROVAL OF PROPOSED FIRST DATABANK CLASS SETTLEMENT AND CERTIFICATION OF SETTLEMENT CLASS**

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## I. INTRODUCTION.

Included within the settlement class for which plaintiffs seek this Court's preliminary approval is the very class for which plaintiffs have a pending motion for class certification against McKesson Corporation ("McKesson"): a class of third-party payors ("TPPs") who were allegedly injured by an increase in average wholesale prices ("AWPs") published by First DataBank Inc. ("FDB") for self-administered drugs purchased or reimbursed by TPPs. Pending the Court's resolution of plaintiffs' motion to certify, McKesson respectfully requests that the Court withhold preliminary approval of the class settlement on the following three grounds:

1. In *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 230 F.R.D. 61 (D. Mass. 2005) ("*Pharm. III*"), the Court denied class certification for the same TPP class suing over self-administered drugs on grounds directly applicable here. Indeed, the present case presents an even stronger case for denying class certification than in *Pharm. III* because of the host of individual causation issues arising out of each TPP's specially-designed reimbursement plans allowing for shifting increases in drug costs to third persons.

2. The proposed FDB settlement provides an agreed-upon class for the Court to give preliminary approval, not one that has been tested by litigation. By first allowing plaintiffs' pending motion to certify to be resolved through briefing by plaintiffs and McKesson, including submission of all relevant evidence obtained through discovery as well as testimony of opposing economic experts, the Court will have a reliable record, which it does not have now, upon which to resolve contested certification issues. Moreover, postponing preliminary approval pending resolution of plaintiffs' pending certification motion will avoid prejudicing McKesson's opposition. The timetable for resolving plaintiffs' pending class certification — which has been extended at plaintiffs' request — can be accelerated by Court order. The orderly administration

of justice will be best served by timely resolving the contested certification motion before, rather than after, preliminary approval of an identical class for settlement purposes.

3. The FDB settlement proposed by plaintiffs is highly controversial, to say the least. To name just a few of the more radical elements of the proposed settlement, it seeks approval of an expanded class not alleged in plaintiffs' complaint, including consumers who this Court already held could not be adequately represented by TPPs; it provides as a remedy the very conduct that the plaintiffs are attacking in this case as fraudulent and in violation of the RICO Act, namely, third parties obtaining FDB's agreement to publish artificial AWPs for the benefit of those parties — here, the TPPs; and it purposely imposes a multi-billion dollar financial burden on persons who are not even parties to the lawsuit and who have never been found to have engaged in any unlawful conduct. Indeed, the proposed settlement is bereft of any analysis of liability or likelihood of success despite providing agreed-upon structural remedies as though the alleged misconduct had actually been proven.

Before the Court puts even its "preliminary" imprimatur on such a radical settlement proposal, the Court should have a complete, litigated record to decide the threshold issue of class certification. This can be easily accomplished by allowing plaintiffs' pending class certification motion to first be resolved ahead of preliminary approval.

## II. THIS COURT'S MDL CLASS RULING TOGETHER WITH THE LIMITED RECORD TO DATE IN THIS CASE COUNSEL AGAINST CERTIFICATION OF THE PROPOSED SETTLEMENT CLASS.

Full consideration of class certification requires completion of discovery and analysis of the contested issues, as contemplated by the briefing schedule and oral argument originally set

by the Court. Nevertheless, plaintiffs' submissions regarding the proposed settlement,[1] the recent deposition in this case of plaintiffs' expert, Raymond Hartman, and this Court's prior class order in the AWP MDL case, *Pharm. III*, already demonstrate the impropriety of certification of the settlement class proposed by plaintiffs. The reasoning of the Court in *Pharm. III* is particularly important because the Court decided that an alleged scheme, like here, to inflate published AWPs causing TPPs to overpay for prescription drugs could not be certified as a class action. *See Pharm. III*, 230 F.R.D. at 65, 69. The Court denied plaintiffs' counsels' motion to certify a nationwide class for TPPs paying for self-administered drugs on grounds directly applicable to plaintiffs' proposed settlement class here. *Id.* at 66, 92-96.

### A. Plaintiffs Seek Preliminary Approval Of A Settlement Class For Which This Court Has Already Denied Certification.

Plaintiffs seek approval of a class for their settlement with FDB for which certification has been denied by this Court in its *Pharm. III* opinion. The fact is, there are even stronger reasons to deny certification here than existed in *Pharm. III*.

#### 1. The Settlement Class Proposed Here Suffers From The Very Same Flaws Which Led The Court To Deny Certification in *Pharm. III*.

In the MDL litigation, the TPP plaintiffs claimed that the drug manufacturer defendants conspired with PBMs to publish through FDB (and other publishers) artificially inflated AWPs for their drugs. This alleged conspiracy defrauded TPPs into believing that the spread between AWP and ASP ("Average Selling Price") was substantially less than was the case. Plaintiffs claimed that the actual spread for self-administered drugs (sold by retail pharmacies) as well as

[1] Settlement Agreement and Release (Docket No. 120); Class Plaintiffs' Memorandum of Law in Support of Joint Motion for Preliminary Approval of Proposed Settlement, Certification of Settlement Class and Approval of Notice Plan (Docket No. 119) ("Settlement Motion Memorandum"); Declaration of Raymond S. Harman [sic]: Impact and Cost Savings of the First DataBank Settlement Agreement (Docket No. 123).

physician-administered drugs, were unknown to TPPs since the ASP of the drug manufacturers was undisclosed. Using a "yardstick" developed by Dr. Hartman for "expected" spreads (up to 30%), plaintiffs claimed that causation and damages could be computed on a class-wide basis; that is, the amount of inflation in AWPs which led to TPPs' overpayments could be calculated using a uniform, formulaic methodology, thereby eliminating individual issues of causation. *Pharm. III*, 230 F.R.D. at 87-88, 94.

With respect to self-administered drugs, this Court disagreed. While this Court in *Pharm. III* granted a class for physician-administered drugs, it denied class certification for self-administered drugs because of the predominance of individual issues of causation. *Pharm. III*, 230 F.R.D. at 92-96. The very same factors which lead to denial of class certification in *Pharm. III* also require denial of certification here.

Specifically, here the TPP plaintiffs also claim that the AWPs published by FDB for self-administered drugs were artificially inflated, in this instance, due to a conspiracy of McKesson and FDB to increase WAC-AWP spreads by 5% (from 20% to 25%). Again, utilizing Dr. Hartman's "formulaic methodologies," plaintiffs claim that as a result of this 5% inflation, TPPs paid nearly 5% more for reimbursement.[2] (Declaration of Dr. Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification, filed July 17, 2006, (Docket No. 77) at 1, 11-14.) ("Hartman Class Cert. Decl.") In Dr. Hartman's opinion, all of the increase in AWPs automatically increased a TPPs' reimbursement costs while all other market factors remain

[2] Actually, Dr. Hartman argues that the additional cost incurred by TPPs was 4.2% x WAC since TPPs are only charged on "average" 85% of AWP (AWP - 15%); in other words, 5% x 85% = 4.2% (Deposition of Dr. Hartman taken in this case on October 4-5, 2006 at 367:20-370:12, hereinafter ("Hartman Dep."), attached as Exhibit 1 to the Declaration of Melvin Goldman in Support of Defendant McKesson Corporation's Opposition to Joint Motion for Preliminary Approval of Proposed First DataBank Class Settlement and Certification of Settlement Class ("Goldman Decl."). Dr. Hartman acknowledges that his methodology involves "simple mathematics," *i.e.*, the assumption that all 5% (or 4.2%) increase was borne directly by TPPs. (Goldman Decl. Ex. 1, Hartman Dep. 370:16-21, 372:19-24.)

unchanged. Key to Dr. Hartman's opinion is his conclusion that the TPPs would not respond to higher AWPs by taking cost shifting action such as negotiating with PBMs new discounts offsetting the increase in AWP.

Yet it is precisely this argument by Dr. Hartman that the Court's own expert, Dr. Berndt, firmly rejected in his February 2005 report to the Court.[3] (Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris at 110-112.) ("Report") Dr. Berndt finds that PBMs play a central role in the context of self-administered drugs; that there is "vigorous" competition among PBMs for the business of TPPs; and that accordingly,

> even if the self-administered AWPIDs were artificially inflated, injury and damages to third party payors do not follow, particularly on a class-wide basis. Since lack of competition among PBMs is crucial to Plaintiffs' theory, this would appear to undermine their allegations, and certainly their assumption of class-wide injury and damages.

(Report at 111.) Dr. Berndt proceeds to the following conclusion:

> In summary, the Plaintiffs' theory in the context of self-administered drugs requires that competition among PBMs be insufficient to prevent injury and damages to third party payors. In my judgment, Plaintiffs have not put forward a convincing argument supporting the notion that competition among PBMs is inadequate. Plaintiffs' contention is also at variance with conclusions reached by the FTC.

(Report at 112-113.)[4] When recently confronted at his deposition in this case with Dr. Berndt's opinion and conclusions, Dr. Hartman took the position that Dr. Berndt and the FTC are simply wrong (Goldman Decl. Ex. 1, Hartman Dep. 195:10-197:25).

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[3] *See* Goldman Decl. Ex. 2, Berndt Report at 110-112.

[4] Dr. Berndt's opinions regarding the relevant market forces involved in reimbursement for self-administered drugs, comport with the Court's own analysis of the market, not coincidentally, relying largely on Dr. Berndt's opinions. The Court found that the presence of PBMs in the distribution-reimbursement chain lead to a host of individual causation issues. As the Court explained, "PBMs are the 800-pound gorillas of pharmaceutical reimbursement." *Pharm. III*, 230 F.R.D. at 71.

Actually, the case here is much stronger for denying certification than in *Pharm. III*. For *Pharm. III*, it was Dr. Hartman's opinion that the spreads between the artificially high AWPs and ASP were not known to TPPs since ASP is kept secret. (Goldman Decl. Ex. 1, Hartman Dep. 81:9-12.) But it is also Dr. Hartman's opinion that had the TPPs been aware of the AWP-ASP spread, "they would use that information to try and negotiate aggressively — if they had known about that." (*Id.* 83:14-84:15.) In other words, the TPPs would have negotiated deeper discounts to offset increased costs. By contrast, in our case the spread between AWP and WAC is readily known and available since both are published by FDB. *See Pharm. III*, 230 F.R.D. at 68; *see also* Goldman Decl. Ex. 1, Hartman Dep. 84:16-85:3. It follows, therefore, that if TPPs knew of the AWP-WAC spread, they would have, in the words of Dr. Hartman, "negotiated aggressively" to eliminate or reduce any increased cost — a decidedly individual issue under Fed. R. Civ. P. 23 (b)(3).

To avoid this inescapable conclusion, Dr. Hartman volunteered at his recent deposition that he personally has "seen no evidence" that any TPP knew of the 5% increase, and that he believes a "preponderance" of TPPs were "unaware" of the increase. (Goldman Decl. Ex. 1, Hartman Dep. 62:10-14, 69:9-70:19). It is also Dr. Hartman's belief that if TPPs were aware, it was not TPPs' "primary focus." (*Id*. 62:15-63:5.) Moreover, it is Dr. Hartman's "assumption" that, in any event, "most" TPPs "could not respond in a way that had any meaning to the 5 percent spread." (*Id*. 67:19-21.) The fact is that each of these additional "opinions" and "assumptions" by Dr. Hartman themselves raise a myriad of individual causation issues — on a TPP-by-TPP basis.[5]

[5] For examples: Did any TPP know of the 5% increase? Did any take action in response to offset any increased cost? If so, was it successful in doing so?

Only two weeks ago, Dr. Hartman admitted as much in his declaration filed in support of the FDB settlement. (Declaration of Raymond S. Harman [sic]: Impact and Cost Savings of the First DataBank Settlement Agreement ("Hartman Settlement Decl.").) There, in footnote 14, Dr. Hartman concedes that if FDB's published AWPs are reduced, from 25% to 20% markups, not all of the potential reduced costs to TPPs would likely occur since it is possible,

> that retailers would attempt to renegotiate the percentage discount off FDB's AWP to defeat the reduction in the allowed amount to be reimbursed. (Hartman Settlement Decl. 5 fn.14.)

Later in footnote 19, Dr. Hartman notes that

> … strategies developed by individual market participants to reverse the effects of the settlement will be developed individually and over time, as different market participants assess their strategic alternatives, observe the strategies of other market participants and ultimately implement their consequential strategies.

What Dr. Hartman foresees from an artificial *lowering* of AWPs obviously applies to our case where it is alleged that AWPs were artificially *raised*. From all that appears, Dr. Hartman has suddenly come to support the view that causation is an individual issue after all.

**2. As in *Pharm. III*, Rebates Create Individual Issues, Too.**

In *Pharm. III*, the Court decided that it was not required to address the above economic issues (*Pharm. III*, 230 F.R.D. at 94), because, like here, individual issues engendered by "rebates" were enough to create predominately individual issues. In its opposition to class certification, McKesson will show that during the Class Period, there are manufacturer rebates which were calculated as a percentage of AWP.[6] If, as alleged, AWPs became inflated due to the

[6] At his deposition in this case on October 4, 2006, Dr. Hartman could not recall whether manufacturer rebates were calculated as a percentage of AWP (Goldman Decl. Ex. 1, Hartman Dep. 177:10-18), whereas in his earlier Declaration in Support of Settlement (dated September 27, 2006, but not provided to McKesson counsel until late on October 4) he opines (in ¶ 12) that they are.

5% increase so, too, did the AWPs used for calculating manufacturer rebates paid to PBMs. (*See* Goldman Decl. Ex. 1, Hartman Dep. 178:22-179:3.) When some or all of these increased rebates were passed on by PBMs to TPPs pursuant to their contracts, the TPPs received an offsetting benefit from the alleged AWP inflation. Accordingly, the individualized nature of rebates paid to TPPs alone makes causation a predominantly individual issue foreclosing class certification, just as in MDL. *See Pharm. III*, 230 F.R.D. at 92-95.

### B. The Facts Here Present A Compelling Case For Denying Certification For Additional Reasons Not Addressed In *Pharm. III*.

The facts here present a still stronger case for denying certification than existed in the MDL due to a variety of contract provisions in TPP-PBM and TPP-member agreements allowing the TPP to shift increased drug costs to third parties. In particular, the agreements between TPPs and PBMs and TPPs and their insureds are tailored (or "designed") to meet the specific needs of the TPP by shifting risks, costs and demand. These contracts provide mechanisms to shift costs from TPPs in a way that eliminates in whole or in part the impact of increased AWPs to the TPP. The following is a brief description of some of these provisions and how they bear on causation.

**Tiered Co-Pays, With 3 and 4 Tiers**. Multi-tier co-pay designs in TPP plans with their member-insureds allow TPPs to shift increased drug reimbursement costs from themselves to their members. By way of example, under a 3-tier system, the TPP may reimburse members generic drug costs less a $5 co-pay in Tier 1; in Tier 2, the TPP may place lower cost, "favored" brand name drugs to be reimbursed at cost less a $20 co-pay; and Tier 3 could contain higher cost, and therefore less favored drugs to be reimbursed at cost less a $30 co-pay. (*See generally* Goldman Decl. Ex. 1, Hartman Dep. 206:7-209:6.) If the cost of a brand name drug in Tier 2 increased (*i.e.*, due to the alleged 5% increase) the TPP could move the drug to Tier 3 — thereby

increasing the co-pay and offsetting the cost to the TPP for the higher AWP. Accordingly, in tiered systems — whose existence Dr. Hartman does not dispute (*Id*. 216:25-217:11) — any impact of the 5% increase could be and likely was offset by changed tiers and additional co-pays.

**Percentage Co-pays**. Whether designed with multiple tiers or not, TPP plans may also provide for percentage co-pays by TPP insureds. *Pharm. III*, 230 F.R.D. at 71 (copayments for self-administered drugs may be "either based on a percentage of AWP or a flat payment"). Therefore, a percentage of any alleged artificial increase in costs to the TPP is shifted to TPP insureds.

**Capitation Provisions.** Under these agreements, the PBM bears some or all of the risks of increased drug costs over the duration of its agreement with the TPP. (*See generally* Goldman Decl. Ex. 1, Hartman Dep. 234:16-236:7.) Thus, where agreed to, the alleged 5% increase could have little or no impact upon the TPP. (*See Id*. 236:4-7 ("If the risk was borne for the inflation by someone other than the TPP then they — then the TPP would not be injured on that")).

These are but a few examples of the means by which TPPs can and do shift to third parties some or all of the increased costs due to increased AWPs.[7]

## III. THE COURT SHOULD AWAIT RESOLUTION OF PLAINTIFFS' PENDING MOTION TO CERTIFY A LITIGATION CLASS BEFORE ADDRESSING SETTLEMENT CLASS CERTIFICATION.

### A. Class Determination Should Be Based on a Fully Developed Record Through the Adversarial Process.

Before granting preliminary approval of the terms of the proposed settlement, the Court must determine whether or not the proposed class can properly be certified. The Supreme Court has held that the primary purpose of Rule 23(a) and (b) is to "focus court attention on whether a

[7] The predominance of individual issues of causation likewise make plaintiffs state law claims not certifiable for self-administered drugs, as the Court found in *Pharm. III*. Further, since the proposed settlement class embraces certification of nationwide state claims, it should be noted that the Court has so far declined to do so. *See Pharm. III*, 230 F.R.D. at 82-86.

proposed class has sufficient unity so that absent members can fairly be bound by decisions of class representatives. That dominant concern persists when settlement, rather than trial, is proposed." *Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 621 (1997). As the Manual for Complex Litigation explains, when class certification is proposed simultaneously with class settlement, it is important to address the class issues first, rather than deferring serious consideration to the final settlement approval stage:

> The better practice is to determine class certification at the preliminary approval stage, thus resolving the central issue of class certification before investing the significant resources required in reviewing what is often a complex settlement agreement and the considerable costs of providing notice to the class.

*Manual For Complex Litigation* § 22.72 (4th ed. 2004).

Where class proponents seek certification of a settlement class before a litigation class is certified, as is the case here, the certification requires heightened scrutiny. Closer scrutiny is required because the settlement process necessarily lacks the adversarial development of a record regarding contested class issues. *Manual for Complex Litigation*, § 21.132 (4th ed. 2004). *See also* 4 Alba Conte & Herbert B. Newberg, *Newberg on Class Actions* § 11.27 (4th ed. 2006). ("approval under Rule 23(e) of settlements involving settlement classes [ ] requires closer judicial scrutiny than approval of settlements where class certification has been litigated.")

In this case, however, there is no need to impose the heightened scrutiny standard, because a litigation class settlement motion is already pending, and the Court can rely on the record developed through the adversary process to adjudicate the proposed settlement class motion. Because the propriety of certifying this class turns primarily on the fact-intensive assessment of whether common issues predominate among the class, the certification decision should not be made until sufficient discovery has taken place such that the Court is able to rigorously consider those issues. *See Lamphere v. Brown University*, 553 F.2d 714, 718 (1st Cir.

1977) (observing that discovery is often appropriate prior to making the certification ruling); *Yaffe v. Powers*, 454 F.2d 1362, 1366 (1st Cir. 1972) (same).

Resolving the litigation class motion before the settlement class motion will not unduly delay proceedings on the motion for preliminary settlement approval. As McKesson proposed in its request for a case management conference, the litigation class motion can be accelerated, and set for hearing as soon as necessary after McKesson files its class opposition on November 17, 2006. If the Court desires a reply and surreply, it can schedule those briefs at whatever intervals the Court deems appropriate.

This case is thus different from those cases where courts certify a settlement class on a conditional basis and await the final settlement stage to more rigorously review the settlement class decision. In those cases there is no prospect of obtaining an adversarial record before the expense of notice is incurred. In this case there is; this Court can have the benefit of a full record for the class issue in a very short period of time. Indeed, this is precisely what this Court's original schedule would have provided for had plaintiffs not requested and obtained a lengthy delay in the original schedule for resolving their certification motion first filed by them in June 2006, some four months ago. Thus, the Court's schedule originally envisioned a hearing on plaintiffs' litigation class motion on November 14, 2006. We can now see that it was after secretly executing their settlement agreement with FDB that plaintiffs requested and the Court acquiesced, and the litigation class motion was set for April 12, 2007. (*See* Memorandum in Support of Def. McKesson Corp.'s Motion Requesting a Case Management Conference, filed October 10, 2006, (Docket No. 127) at 4 and n.7.)

**B. Resolving the Settlement Class Before Reviewing the Fully Developed Record on the Contested Litigation Class Is Prejudicial to McKesson.**

The requirements of Federal Rule 23(a) and (b) apply equally to a proposed settlement class as they do to a proposed litigation class, except that the court need not consider whether a settlement class would present intractable management problems at trial. *Amchem Prods. Inc. v. Windsor*, 521 U.S. 591, 619-20 (1997). Plaintiffs acknowledge this by relying for Rule 23 certification (under Rule 23(b)(1), (b)(2) and (b)(3)) on the very same memorandum of law for both motions.[8] Rule 23(b)(3) in particular requires, among other things, that questions of law or fact common to the members of the class predominate over questions affecting only individual members. In the context of a settlement class, common issues must predominate without regard to what has been resolved in the settlement. *See, e.g., Hanlon v. Chrysler Corp.*, 150 F.3d 1011, 1022 (9th Cir. 1998); *Krell v. Prudential Ins. Co. of Am.*, 148 F.3d 283, 309 (3d Cir. 1998). *See also Manual for Complex Litigation*, § 21.132 (4th ed. 2004). Thus, consideration of whether common issues predominate in the non-adversarial settlement context, without McKesson first having a full opportunity to brief the contested class issues, would unduly prejudice McKesson.

Plaintiffs cannot distinguish the issues arising with respect to the settlement class from the litigation class by arguing that the settlement offers only injunctive relief (*i.e.*, Rule 23(b)(1) and (b)(2) versus Rule 23(b)(3)). (*See* Plaintiffs' Memorandum in Response to Def. McKesson Corp.'s Motion Requesting a Case Management Conference, filed October 18, 2006 (Docket No. 134) at 6.) Plaintiffs' proposed settlement expressly seeks certification of a settlement class under Rule 23(b)(3) as well as under Rule 23(b)(1) and (2). Thus, the requirement of predominance of common issues applies equally to the settlement class as it does to the litigation

[8] *See* Plaintiffs' Memorandum in Support of Class Certification [Docket No. 76] and Plaintiffs' Memorandum in Support of Class Settlement at 14, n.4 (relying on Docket No 76).

class plaintiffs seek to certify. Moreover, on their face the settlement terms that plaintiffs characterize as "injunctive" are nothing more than disguised damages through future cost reductions. The AWP rollback plaintiffs propose in the settlement is designed to provide billions of dollars in monetary recovery to the very class of individuals (and others) whom plaintiffs claim lost money as a result of the alleged scheme to inflate AWPs. These same individuals are then required to release their claims for monetary damages against FDB.

As demonstrated above, at the very least, serious questions exist as to whether the proposed settlement class satisfies Rule 23(b)(3)'s requirement that common questions of law and fact "predominate" over individual questions. Fed. R. Civ. P. 23. This Court "must conduct a rigorous analysis of [those prerequisites] before certifying a class." *Smilow v. Southwestern Bell Mobile Sys.*, 323 F.3d 32, 38 (1st Cir. 2003). In reaching that determination, "[t]he court should provide an adequate opportunity for proponents and opponents to make a full showing of all relevant matters." 4 *Newberg on Class Actions* § 11.27; *Manual For Complex Litigation* § 21.632 ("In settlement classes [ ] it is often prudent to hear not only from counsel but also from the named plaintiffs, from other parties, and from attorneys who represent individual class members but did not participate in the settlement negotiations.").

Because there is already pending before this Court plaintiffs' motion to certify, there is no reason to rush determination of the settlement class question, and lose the benefit of a fully developed adversarial record that will be before the Court in just 4 weeks.

### C. Awaiting a Full Class Record Is Particularly Warranted Here Because of the Questionable and Obviously Controversial Nature of the Settlement Proposed.

The proposed settlement has a number of controversial and highly questionable components that counsel even more strongly for particular care and due deliberation in certifying the proposed settlement class as part of granting preliminary approval to the settlement. These

factors relate to both the dramatically expanded class and claims addressed in the settlement, as well as the extraordinary redistribution of reimbursement costs, beyond the parties to the litigation, sought by the settlement remedy. Briefly, they include the following.

**1. The Proposed Settlement Impermissibly Extends Beyond the Class and Claims Pled In This Litigation.**

On its face, the proposed settlement goes far beyond the purported class and claims alleged in the litigation. Plaintiffs, however, offer no justification for this expansion. On this basis alone, the settlement is suspect.

A comparison of the proposed litigation class with the settlement class is instructive. The litigation class is defined as:

> All third-party payors whose pharmaceutical payments and/or purchases for the Subject Drugs were based on AWP during the Class Period. The Subject Drugs are the brand named drugs identified in Exhibit A.

(Corrected Plaintiffs' Motion for Class Certification at 1 (Docket No. 99, filed July 27, 2006). Yet the Settlement Agreement defines the proposed settlement class with a much broader brush:

> All individual persons or entities who, during the Class Period, made purchases and/or paid, whether directly, indirectly, or by reimbursement, for all or part of the purchase price of prescription pharmaceuticals, including but not limited to, those pharmaceuticals listed on the attached Exhibit A, where any or all of the purchase price, reimbursement or payment amount was based in any part on the Average Wholesale Price, Blue Book Average Wholesale Price or similar data published or disseminated by First DataBank, Inc., electronically or otherwise, and which such Average Wholesale Price, Blue Book Average Wholesale Price or similar data published or disseminated by First DataBank, Inc., electronically or otherwise, in whole or part was based on a FDB wholesale survey.

(Settlement Agreement and Release at 4.) The proposed settlement class thus expands the parties whose claims will be extinguished in two dramatic ways:

- Unlike the class alleged, which includes only TPPs, the settlement class includes consumers, physicians and PBMs "who made purchases and/or paid, whether directly, indirectly, or by reimbursement, for all or part of the purchase price of prescription pharmaceuticals." (Settlement Agreement and Release at 4; *see also* Settlement Motion Memorandum at 14.)

- Unlike the class alleged, the proposed settlement is not limited to payors of prescription drugs who paid an amount based upon FDB's published AWPs. Rather, the settlement class also includes individuals and entities who paid "based upon FDB's published WAC . . . ." (*See* Settlement Motion Memorandum at 14.)

Beyond the class definition, the proposed settlement also attempts to alter the structure for reimbursement with respect to claims that have never been made in this litigation. The proposed settlement mandates a remedy that applies not just to the more limited number of NDCs for self-administered brand name drugs listed on Exhibit A to the FAC; it also seeks to fix the price of AWPs on 6,828 additional NDCs, which plaintiffs refer to as all "prescription pharmaceuticals," including generics and physician-administered drugs not involved in this lawsuit. (*See* Settlement Agreement and Release at 4, 19, Ex. A; *see also* Hartman Settlement Decl. at 2 n.8.) This is five times the number of NDCs identified in the FAC. Settlement Motion Memorandum at 10. There are no allegations in the complaint that suggest any violation of law related to anything other than the self-administered specified drugs listed in Exhibit A.[9]

In language directly applicable here, the First Circuit has held that a court cannot lend its imprimatur to a settlement unless:

> (1) it 'springs from and serves to resolve a dispute within the court's subject matter jurisdiction'; (2) it 'comes within the general scope of the case made by the pleadings'; and (3) furthers the objectives upon which the complaint was based.

*United States v. Charles George Trucking*, 34 F.3d 1081, 1089 (1st Cir. 1994) (quoting *Local No. 93, Int'l Ass'n of Firefighters v. Cleveland*, 478 U.S. 501, 525-26 (1986)). Plainly, the scope

[9] Indeed, even within the category of self-administered brand-name drugs, plaintiffs do not dispute that some of those drugs had WAC to AWP spreads of 25% for reasons completely unrelated to the scheme alleged in the FAC, and thus those drugs had been excluded from the class alleged in the FAC.

of the settlement class as well as the enlarged class of claims made, run afoul of these settlement requirements.

**2. The Proposed Settlement Impermissibly Imposes Billion Dollar Costs on Entities who are Not Parties to this Litigation.**

Plaintiffs and Dr. Hartman argue that the settlement will provide billions of dollars of benefits to TPPs in the form of lower reimbursement costs as a result of the fixing of AWPs at a 20% markup over WAC. Who do plaintiffs expect will bear this financial burden? According to plaintiffs' settlement papers, the benefit will be exacted from unnamed entities, not parties to this litigation, such as PBMs and retail pharmacists to whom TPPs pay for the provision of prescription drugs to their members. (*See* Hartman Settlement Decl. ¶ 5.)[10]

**3. The Proposed Settlement Purports to Provide a Cure for a Claim for Which No Liability Has Been Established.**

Apart from the cost shifting to third parties, the settlement seeks to mandate this cost-shift without any determination of whether the AWPs were artificially inflated in the first place. Indeed, FDB continues to deny any liability, as a condition of the settlement. Not even Dr. Hartman has weighed in on the issue of liability. Indeed, at his recent deposition in this case he stated he had not considered any analysis of liability. (Goldman Decl. Ex. 1, Hartman Dep. 6:14-20.)

**4. The Proposed Settlement Seeks Approval of the Very Conduct Alleged by Plaintiffs to be Illegal.**

In this case, plaintiffs allege that McKesson fraudulently conspired for its benefit with FDB to artificially *raise* AWP in violation of the RICO statute and state laws. Here, in plaintiffs' proposed settlement, a group of TPPs purport to do exactly that — only here it is to

[10] Also, while Dr. Hartman presumes these TPP-PBM-Retailer contracts will be based upon FDB AWPs, as shown above, he ignores that the percentage discounts in these contracts have changed as a result of increases in AWP prices. Thus, plaintiffs "remedy" will lower AWPs but not change the larger discounts negotiated on the basis of higher AWPs.

artificially *lower* AWPs for the TPPs' benefit. Under plaintiffs' own theory, they are asking the court to approve conduct plaintiffs believe is illegal. What's more, because TPPs in the class undoubtedly compete, their agreement on AWP pricing raises additional concerns under federal antitrust laws.

Taken together, these concerns certainly warrant close scrutiny of the class certification issue upon which the entire settlement rests. This Court should not rush the preliminary determination of the settlement class and settlement where, as here, there are serious questions of legality regarding the proposed settlement agreement and its efforts to shift costs to third parties.

## III. CONCLUSION

The settlement proposed by plaintiffs and FDB requires careful scrutiny. At the very least the Court should permit full discovery and full discovery and resolution of plaintiffs' pending certification motion (as originally planned) before giving preliminary approval to the much broader, consensual settlement class. Of particular relevance to that outcome is the fact that the litigation class is subsumed completely within the settlement class and that this Court previously denied certification of an almost identical litigation class.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that a true copy of the above document was served upon the attorney of record for each other party through the Court's electronic filing service on October 18, 2006.

/s/ Lori A. Schechter
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